Lab Call
4/8/04

Topic: Protocol for validating the commutability of the NIST Creatinine Reference Material

Participants: Gary Myers, Sam Caudill, Elisa Gladstone, John Eckfeldt, Neil Greenberg, and Greg Miller

Next Steps:

- Neil is working with the program director at the AACC to use their channels of distribution for the invitation letter for the Manufacturer's Forum at the AACC meeting.
- Laura will create a PDF of the AACC invite letter and send to Neil for dissemination.
- John will prepare a clinical history data input form for the patient samples.
- Sam and Gary will begin developing a data input form that could potentially be web-based.
- Elisa will find out how the IRB process works through NIH.
- John will put together a protocol with the basic information on the study for IRB purposes.
- Greg will call Pat Clapshaw to see where things stand with the extra pilot materials.
- Elisa will contact Pat Clapshaw to see how we go about paying NIST for the overrun of serum materials.
- Greg will provide an estimate of costs to collect and process individual donor serum for the panel of frozen aliquots (25 ml blood from each donor.

Discussion:

Sam reviewed the statistical models that he circulated by email, which the group found very helpful in understanding the role of increasing sample number and replicate analyses. The general conclusion was that increasing the number of different patient serum specimens above 20 seems not to increase the power much for finding non-commutability, but increasing the replicates from 2 to 5 improved the power considerably. The general consensus was to try a protocol of 40-50 patient samples spanning about 0.7 to 4.5 mg/dL creatinine with the samples roughly equally distributed across the concentration range and try analyzing them 5 times by the field method. Based on this data, then see if 20 patient samples in triplicate will work adequately as the statistical modeling predicts. Serum samples shown to be outliers (i.e., giving values far off the regression line) and be deleted from the final set used for determining commutability.

Potential hold up will be NIST's assignment of reference method values to the 40-50 patient samples and getting IRB approval for collection of serum samples from patients with renal failure. Each renal failure patient will have to donate about 25 mL of blood so perhaps 50 0.25-mL aliquots of each patient's serum can be produced and stored at -70 C.